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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/057,016	04/07/98	TURPEN	1 801.87US01
EXAMINER			

HM21/0803

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FOX P	PAPER NUMBER
ART UNIT	4

1649

DATE MAILED: 08/03/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on _____

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire — 3 — month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 14-17 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 14-17 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on 4/7/98 is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

—SEE OFFICE ACTION ON THE FOLLOWING PAGES—

Art Unit: 1649

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1649.

Applicants' claim of priority to prior applications is noted. The last sentence of the paragraph added to page 1 of the specification by the amendment of 07 April 1998, "Benefit is claimed...1988" should be deleted as it is redundant.

Applicants' attempt to claim benefit of the earliest filing date, 26 February 1988, in parent application Serial No. 08/324,003 is noted. However, the applications with that filing date, Serial Nos. 07/160,766 and 07/160,771, are completely silent with regard to the production of a fusion protein from a viral vector. Lines 30-33 of page 12 of 07/160,766, referred to on page 8 of the amendment of 22 November 1996, disclose the insertion of a second sequence, corresponding to a heterologous gene of interest, into a first sequence corresponding to a viral genome, wherein the second sequence is inserted directly adjacent to an already existing viral promoter, or wherein a viral promoter may be attached to the second sequence before insertion into the viral genome. In either case, only a single discrete protein from a single source (the second nucleotide sequence) would be expressed by the second nucleotide sequence under the control of its adjacently associated promoter. This is not a fusion protein.

Application Serial No. 07/219,279 filed 15 July 1988 is similarly silent with regard to the production of a fusion protein, being drawn to the use of non-infective viral vectors with their coat protein genes partially or completely deleted and with a foreign gene inserted into the viral

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genome immediately adjacent to a viral promoter, usually at the site of a completely deleted coat protein gene, as was done in the above-mentioned applications.

Application Serial No. 07/310,881 filed 17 February 1989 is the earliest filed application which discloses the production of a fusion protein by a viral vector, at Example 3 on page 44. Thus, claims broadly drawn to the production of a fusion protein by a viral vector are accorded the effective filing date of 17 February 1989.

None of the prior applications referred to by the amendment to the specification of 07 April 1998, other than the most recent parent application Serial No. 08/324,003, disclose the use of leaky stop codons for the production of fusion proteins by a viral vector, as claimed in claims 14-17 of the instant application. Some of the later filed applications mention the use of linker sequences encoding protease cleavage sites for the separation of the desired protein from the viral protein of the fusion protein. This is a completely different concept. Thus, the effective filing date for this aspect of the claimed invention is the filing date of the most recent parent application, 14 October 1994.

The declaration filed with the instant application is defective for its omission of the parent applications referred to in the preliminary amendment of 7 April 1998. A substitute declaration should be submitted.

Claims 14-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of copending Application No. 08/324,003. Although the conflicting claims are not identical, they are not patentably distinct

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from each other because it would have been obvious to one of ordinary skill in the art to utilize the polynucleotide encoding a fusion protein comprising a tobamovirus coat protein linked to a heterologous protein by a leaky stop codon under the control of a plant-expressible promoter, as claimed in the copending application, to obtain the plant transformation vector and virion comprising said polynucleotide, and methods for its use to transform plants, as claimed in the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Applicants' attempts to provoke an interference with U.S. Patent 5,618,699 is noted.

However, as indicated above, the effective filing date afforded to Applicants for the instantly claimed invention is 14 October 1994, which is over one year later than the effective U.S. filing date of the patent which was filed under 35 USC 371, namely 31 March 1993, the filing date of

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the PCT application. See MPEP 2308.01, page 2300-20, column 2, first full paragraph.

Accordingly, a showing under 37 CFR 1.608(b) is required in order to provoke an interference.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 14-17 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Hamamoto et al, U.S. Patent 5,618,699 (see, e.g., claims 1, 9, 13 and 16).

Note that the claims in parent application Serial No. 08/324,003 were deemed free of the corresponding Hamamoto *et al.* journal article because those claims were broadly drawn to fusion proteins which did not comprise a readthrough sequence, and were thus afforded the earlier filing date of 17 February 1989.

Since the effective filing date of the instant application is more than 3 months after the effective filing date of the patent, 37 CFR 1.608(b) requires that the applicant must file (1) evidence, such as patents, publications and other documents, and one or more affidavits or declarations which demonstrate that applicant is *prima facie* entitled to a judgement relative to the patentee, and (2) an explanation stating with particularity the basis upon which the applicant is *prima facie* entitled to the judgement. The patent cannot be overcome by an affidavit or declaration under 37 CFR 1.131 but only through interference proceedings. See MPEP 2308.01.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Douglas Robinson, can be reached on (703) 308-2897. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

July 28, 1998

DAVID T. FOX
PRIMARY EXAMINER
GROUP 130 1649

David T. Fox